

Organization IC1600 Bldg/Rooftop REMSSEN

United States Patent and Trademark Office

P.O. Box 1450

Alexandria, VA 22313-1450
If Undeliverable, Return in Ten Days

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, \$300

AN EQUAL OPPORTUNITY EMPLOYER

for FILED FRC, M ZIP COD.

§ 00

OCT C

42641-5

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72

72



RECEIVED
OCT 10 2006
PATENT AND TRADEMARK OFFICE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,727	02/02/2004	Rong-Kun Chang	SHLI-035-002	1013
7590	10/03/2006		EXAMINER	
Elisa Lane Shire Laboratories Inc. 1550 East Gude Drive Rockville, MD 20850			LEWIS, PATRICK T	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/770,727	CHANG, RONG-KUN
	Examiner	Art Unit
	Patrick T. Lewis	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>05072004</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gidwani et al. US 6,828,334 (Gidwani).

Claims 1-10 are drawn to a pharmaceutical composition comprising a solubilizing agent selected from crystalline methylated α -, β -, and γ -cyclodextrin, or mixtures thereof, and a pharmaceutically active agent. Claim 2 limits the cyclodextrin. Claims 3 and 10 limit the active agent. Claims 4-9 limit the type of formulation (i.e. oral, parenteral, etc.)

Gidwani teaches a pharmaceutical composition containing fenofibrate in the form of an inclusion complex with methylated beta cyclodextrin (Example 6). The inclusion

complex can be administered as pharmaceutical formulations in form of tablets or in the form of granules inside a capsule (column 5, lines 20-45).

Gidwani differs from the instantly claimed invention in that 1) Gidwani is silent on the use of a crystalline cyclodextrin and 2) Gidwani does not teach liquid formulations.

Mere recitation of newly-discovered function or property (i.e., physical form), inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art; Patent Office can require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; this burden of proof is applicable to product and process claims reasonably considered as possessing allegedly inherent characteristics. Patent and Trademark Office does not have facilities for examining and comparing applicant's various claimed crystalline forms with the prior art, and thus applicants have the burden of persuasion to make some comparison between materials in order to establish unexpected properties crystalline forms of methylated beta-cyclodextrin. Formulation of the composition of Gidwani into a cream or liquid is well within the purview of one of ordinary skill in the art.

Conclusion

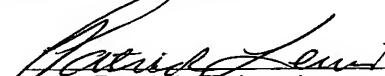
4. Claims 1-10 are pending. Claims 1-10 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

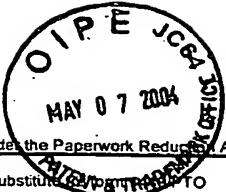
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Dr. Patrick T. Lewis
Primary Examiner
Art Unit 1623

ptl



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Approved for use through 07/31/2006, OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
is a collection of information required by 37 CFR 1.13. OMB Control No. 0651-0031.

Substituted by Part 1A PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Application Number	10/770,727
		Filing Date	February 2, 2004
		First Named Inventor	CHANG
		Art Unit	not yet assigned
		Examiner Name	not yet assigned
		Attorney Docket Number	SHLI-035-002

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Examiner Signature *[Signature]* **Date Considered** *9-27-06*

"EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.¹ Applicant's unique citation designation number (optional).² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Notice of References Cited		Application/Control No.	Applicant(s)/Patent Under Reexamination	
		10/770,727	CHANG, RONG-KUN	
Examiner		Art Unit		Page 1 of 1
Patrick T. Lewis		1623		

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,828,334	12-2004	Gidwani et al.	514/338
*	B	US-6,464,988	10-2002	Gidwani et al.	424/400
*	C	US-5,472,954	12-1995	Loftsson, Thorsteinn	514/58
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.